

Marked-Up Claims
for
09 585.475

1. (Amended) A method for determining a degree of toxicity or efficacy of an agent candidate not previously known to have toxicity or efficacy comprising:
exposing a tissue of interest in a subject to the agent such that the agent contacts said tissue of interest.

obtaining a test biological sample containing protein from said tissue of interest.

measuring levels of protein markers of toxicity or efficacy in said sample, and
comparing the levels of said markers to the levels of the same markers in a control sample or other sample exposed to known toxic or known effective agents to determine whether the tissue of interest in a subject is experiencing toxicity or an effective response or the degree of such responses.

4. (Amended) The method of claim 1 further comprising:

measuring levels of individual proteins in a proteome of said biological sample from the tissue of interest.

comparing these levels with levels of the same proteins in the proteome from a sample from a tissue of interest from a control subject or a subject treated with one or more other agents known to be toxic or effective, and

detecting which [proteins] protein levels are increased or decreased by a statistically significant amount.

5. (Amended) The method of claim 1 wherein the statistically significant amount is determined [as a] at $p < 0.01$.
10. (Amended) The method of claim 1 wherein the levels of protein markers in the test biological sample [is] are compared to the levels of the same protein markers in biological samples exposed to a known effective agent or known toxic agent.
11. (Amended) The method of claim 4 wherein the levels of protein markers in the test biological sample [is] are compared to the levels of the same protein markers in biological samples exposed to a known effective agent or known toxic agent.
12. (Amended) The method of claim 4 wherein said individual proteins in said proteome [is] are [prepared] separated by two-dimensional electrophoresis.
13. (Amended) The method of claim 1 wherein the comparing is to the control and the control is a biological sample [contain] containing protein from the same tissue of interest before the tissue of interest is exposed to the agent.